IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED CARDIOVASCULAR SYSTEMS, INC. and GUIDANT SALES CORPORATION,	)	
Plaintiffs,	)	C. A. No. 98-80 (SLR) (Consolidated with C. A. No. 98-314 (SLR) and C. A. No. 98-316 (SLR))
v.	)	
MEDTRONIC VASCULAR, INC. and MEDTRONIC USA, INC.,	)	
Defendants.	)	

MEDTRONIC'S OPENING BRIEF IN SUPPORT OF ITS RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW

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NATURE AND STAGE OF PROCEEDINGS

These consolidated cases were filed in Delaware in 1998 (D.I. 1 (Complaint filed 2/18/98)). Before trial, the Court granted summary judgment in favor of Advanced Cardiovascular Systems, Inc. and Guidant Sales Corporation (collectively, "ACS") on the claims of Medtronic Vascular, Inc. and Medtronic USA, Inc. (collectively, "Medtronic") for infringement of its Boneau patents and various state law claims relating to ACS's misuse of confidential information regarding the Boneau invention. (D.I. 544 & D.I. 546). From February 7 to 18, 2005, the Court held a 9-day trial on the remaining legal issues in the case, namely, ACS's claims that Medtronic's stents infringe the asserted claims of various ACS patents and Medtronic's counterclaim that ACS's patents are invalid as obvious and anticipated.[1] The Court has scheduled a two-day hearing on June 7-8, 2005, with respect to Medtronic's inequitable conduct claim.

Medtronic moved for judgment as a matter of law ("JMOL") at the close of ACS's case and again at the close of evidence. (D.I. 598; Trial Tr. at 1678:9-1680:11 & Dkt Entry of 2/16/05). ACS also moved for JMOL at the close of all evidence. (D.I. 621, DI. 622 & Trial Tr. at 1680:12-1683:4). The Court denied the parties' JMOL motions with the exception of Medtronic's motion as to no infringement by equivalents and ACS's motion as to anticipation. (Dkt Entry of 2/17/05 & Tr. at 1739:20-1740:1). On February 18, the jury

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[1] The asserted claims are claims 1, 4 and 12 of U.S. Patent No. 5,512,154 (the "'154 patent"); claims 5 and 8 of U.S. Patent No. 6,066,167 (the "'167 patent"); claims 1, 3 and 11 of U.S. Patent No. 6,066,168 (the "'168 patent"); and claims 1, 2, 3 and 9 of U.S. Patent No. 6,432,133 (the "'133 patent"). The text of the asserted claims is set forth in Exhibit A to this brief.

As referred to here, the "Lau patents" means these patents in suit (and the asserted claims) as well as, to the extent appropriate in context, other patents issuing from the same original application (Ser. No. 07/783,558, filed Oct. 28, 1991).

returned a verdict that the ACS patents are not invalid and that Medtronic's accused products[2] infringe the asserted claims. (D.I. 629). The Court yet to enter judgment on the jury verdict.

By Order dated March 11, 2005, the Court directed the parties to file any post-trial motions by April 18, 2005. (D.I. 643). This is Medtronic's opening brief in support of its renewed motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(b).

SUMMARY OF ARGUMENT

Based on the evidence ACS introduced at trial, no reasonable juror could have found the Medtronic accused products infringe any of the asserted claims because:

- The Medtronic stents do not have spaced apart "cylindrical elements" with an "undulating pattern" as those terms are properly construed.
- Medtronic's stents do not have the "connecting elements" required by the claims of the '154 patent.
- ACS failed to show that any stents (other than the Driver and MicroDriver) meet the limitations in all asserted claims of a "longitudinally flexible stent" with "expandable cylindrical elements" with length less than diameter.
- ACS failed to show that any of Medtronic's stents were made, used, sold or offered for sale during the term of the asserted patents.
- ACS failed to show that it owns the asserted patents.

Each of these grounds independently justifies entry of JMOL of non-infringement (an issue as to which ACS bore the burden of proof).

For its part, Medtronic presented clear and convincing evidence that the asserted claims are invalid under Section 103 for obviousness. ACS failed to effectively rebut this evidence. Because no reasonable jury could have found the patents valid in view of this

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[2] The "Medtronic accused products" or "Medtronic stents" are the MicroStent II, GFX, GFX2, GFX 2.5, S540, S660, S670, BeStent2, S7, Driver, MicroDriver and Racer.

evidence, Medtronic asks that the Court also enter JMOL that the asserted claims Lau patents are invalid as obvious.

STATEMENT OF FACTS

Facts related to each of the grounds upon which Medtronic moves for JMOL are set out in the corresponding sections of the Argument.

ARGUMENT

I. BECAUSE MEDTRONIC'S STENTS LACK THE SPACED APART AND EXPANDABLE "CYLINDRICAL ELEMENTS" AND "UNDULATING PATTERN" OF THE LAU PATENT CLAIMS (AS PROPERLY CONSTRUED), THEY DO NOT INFRINGE

A. Legal Standard And Summary Of Argument

Judgment as a matter of law is proper if "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a). *See Northview Motors, Inc. v. Chrysler Motors Corp.*, 227 F.3d 78, 88 (3d Cir. 2000). In a patent infringement action, "JMOL of non-infringement is properly granted if no reasonable jury could have concluded that a limitation recited in the *properly construed* claim is found in the accused device, either literally or under the doctrine of equivalents." *Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc.*, 248 F.3d 1303, 1309 (Fed. Cir. 2001). (Emphasis in quoted material throughout is added unless otherwise noted.)

Here, all of the asserted claims require "cylindrical elements," and the common specification of the asserted Lau patents describes those cylindrical elements as being ***spaced apart*** from one another. As originally construed, the Court defined the "undulating pattern" which forms the cylindrical elements as requiring a combination of U-shaped, W-shaped, and Y-shaped members. At ACS's urging, however, the Court withdrew that construction and

instructed the jury instead that an "undulating pattern" is simply a pattern that is "wavelike," thus omitting any requirement that the cylindrical elements be spaced apart.

Under the proper construction, Medtronic's stents do not infringe ACS's patents. Because no reasonable jury could have found infringement of the cylindrical element limitation, as properly construed, the Court should grant JMOL of non-infringement.

B. Properly Construed, The "Undulating Pattern" Of The "Cylindrical Element" Found In All Asserted Claims Must Have A Combination Of U-Shaped, W- Shaped And Y-Shaped Members

1. The Specification Of The Lau Patents Makes Clear That The "Undulating Pattern" Must Be Comprised Of A Combination Of U-, W- and Y-Shaped Members

The Court need look no further than the common specification of the Lau patents to see that the cylindrical elements described in the Lau patents must have a combination of U-shaped, W-shaped and Y-shaped members because a crucial element of the invention – and what ACS considered to be new – was a series of short, cylindrical elements *spaced apart* by connectors to provide longitudinal flexibility.

This is made clear in the "Summary of the Invention" where ACS described "the stent of the invention." After describing the general components of the invention (*see, e.g.*, AX1 at 1:59-2:1), ACS stated that:

> The resulting stent structure is a series of radially expandable cylindrical elements *which are spaced longitudinally close enough* so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall *but not so close as to comprise the longitudinal flexibilities* of the stent.

(*Id.* at 2:1-6). ACS was unequivocal. By referring to what "resulting stent structure is" – rather than "may be" or "preferably is" – ACS made clear that this structure was not just a preferred embodiment, but the fundamental structure that is common to every embodiment of

its invention. And by stating that the cylindrical elements must be spaced "*not so close* as to compromise the longitudinal flexibilities of the stent," ACS made clear that *there must be space between cylindrical elements*. It is the presence of Y- and W-shaped members, with portions extending between cylindrical elements, that provides the spacing required by the Lau patents. Thus, the stent of the invention must have some combination of U-shaped, Y-shaped and W-shaped members.

2. The Figures Of The Lau Patents Support A Construction Requiring A Combination Of U-, W- and Y-Shaped Members

The figures of the ACS patents support this construction. As Medtronic demonstrated at trial, each of the figures which shows the cylindrical elements has a *combination* of U-shaped, W-shaped, and Y-shaped members. ACS's description of the figures during prosecution confirms they were intended to depict cylindrical elements in the form of a serpentine pattern specifically defined as being made up of a plurality of U-shaped, W-shaped, and Y-shaped members:

> *In keeping with the invention*, and with reference to FIGS. 4 and 12-14, cylindrical elements 12 are in the form of a serpentine pattern 30. As previously mentioned, each cylindrical element 12 is connected by interconnecting elements 13. Serpentine pattern 30 is made up of a plurality of U-shaped members 31, W-shaped members 32 and Y-shaped members 33, each having a different radius so that expansion forces are more evenly distributed over the various members.

(*Id.* at 6:8-16).[3]

The description of the figures further confirms that the term "serpentine" and

[3] Although this passage specifically refers to Figures 4 and 12-14, which were added to the '154 patent application, this passage makes clear that these figures are "in keeping with the invention."

"undulating" were used interchangeably throughout the specification. In describing Fig. 11 in the Brief Description of the Drawings, ACS stated that the figure showed an "alternate undulating pattern." (AX1 at 4:5-6). In the Detailed Description of the Preferred Embodiments, ACS described the same figure as showing a "serpentine pattern." (AX1 at 5:63-65). Thus, the embodiment that has a combination of U- and Y-shaped members is alternately called "undulating" and "serpentine." Figures 5 and 11 of the '154 patent provide further evidence that ACS intended the "undulating pattern" (and, therefore, "cylindrical element") to refer to a combination of at least two of the three letter-shaped members and not merely a collection of U-shaped members.

In the "Brief Description of the Drawings," ACS described Figure 5 as illustrating "the undulating pattern" of the stent. (AX1 at 3:61-63). Figure 5 shows an undulating pattern made up of U-shaped, W-shaped and Y-shaped members. ACS described Figure 11 as illustrating "an alternate undulating pattern" of the stent. (AX1 at 4:5-7). Figure 11 contains only U-shaped and Y-shaped members.

FIG. 5

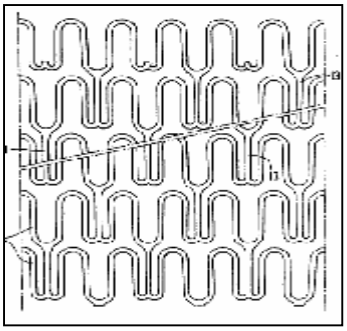
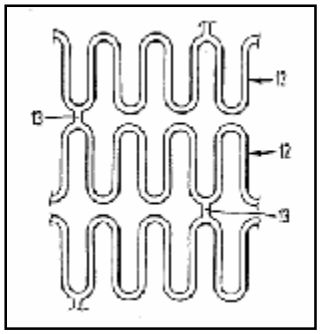


FIG. 11



By describing Figure 11 as depicting an "*alternate* undulating pattern," ACS stated that the undulating patterns in the two figures differ. It follows that "undulating pattern" means something more than just "wavelike." The "wavelike" portions of Figure 5 and Figure 11 are the same sinusoidal pattern. It is only the presence of the W- and Y-shaped members

that makes the cylindrical elements, taken as a whole, different from (and "alternate" to) one another. If one were to ignore the connectors that make up an integral part of these patterns, they would not be "alternate" patterns at all, but the same pattern (a series of U-shaped members in a ring configuration). By talking about "alternate" designs in the context of Figures 5 and 11, ACS necessarily drew attention to what distinguished those designs from each other (that is, the configuration of the connectors) and not what they had in common.

3. The Prosecution History Confirms That The Claims Require A Combination Of U-, Y-, And W-Shaped Members

a. ACS Attempted, Unsuccessfully, To Get The Patent Office To Issue Claims Based On A Specification With No Mention Of U-, W- And Y-Shaped Members

Lilip Lau and the other named inventors filed their original patent application (U.S. Ser. No. 07/783,558 (the "'558 application")) on October 28, 1991. The claims of that application were directed to stents and methods for making a stent. After the examiner imposed a restriction requirement, ACS chose to proceed with apparatus claims directed to the stent. Ultimately, the Patent Office rejected the claims in the '558 application, and ACS abandoned them, but not before filing a continuation application (U.S. Ser. No. 08/164,986) on December 9, 1993. In this second application, ACS continued to pursue apparatus claims, but they too were ultimately rejected and abandoned. (AX9 at 140-44 and 147).

b. ACS Was Forced To Add U-, W- And Y-Shaped Members To Its Specification

After the Patent Office rejected ACS's apparatus claims for a second time, ACS filed U.S. Ser. 281,790 (the "'790 application"), a continuation-in-part application adding "new

matter" which defined the shape of the cylindrical elements to get its claims issued.[4] Ultimately, this application matured into the '154 patent, the first-issued of the asserted patents. Each of the remaining asserted patents is related to the '154 patent through continuation and/or divisional applications and share a common specification.

As noted above, in the original '558 application, each figure which illustrated the cylindrical elements of the invention had a combination of U-shaped, Y-shaped, and W-shaped members. (*See, e.g.*, Exh. B, Figs. 2-5 & 7-11 which were also in the original applications). The original application also described the shape of the cylindrical element as "serpentine" (AX8 at 352:4-6, 360:8-11), but did not define "serpentine." (This same language was in the '154 application. (Exh. B at 7:18-21 and 14:8-17).)

To get apparatus claims based on its pending application, ACS had to cure this deficiency. Accordingly, ACS, acting as its own lexicographer, added language to clarify that the cylindrical elements are in the form of a serpentine pattern, and that the serpentine pattern is "made up of a plurality of U-shaped members, W-shaped members and Y-shaped members." (AX11 at 15). ACS further described how these members project outward radially "to form projecting edges when the stent is expanded." (AX11 at 14-15). ACS added Figures 12-14 to the application specifically to illustrate this language relating to U-, W- and Y-shaped members. **(**AX11 at 10-11, 33). (ACS made clear, however, that the serpentine pattern of these figures was "[i]n keeping with the invention.") These figures show the outwardly projecting edges which form when the serpentine pattern is expanded by a balloon, as well as the W- and Y-shaped members that space the cylindrical elements apart.

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[4] Attached as Ex. B to this brief is a copy of the continuation-in-part application in which the "new matter" is highlighted.

c. ACS Convinced The Patent Office To Issue The Asserted Claims Based On The Added Language About U-, W- And Y-Shaped Members

After adding this "new matter" to its pending application, ACS repeatedly argued to the Patent Office that the "cylindrical elements" of its invention had an "undulating pattern" made up of a combination of these U-, W-, and Y-shaped members to gain allowance of its claims. For example, in January 1995, when the Patent Office objected to application claim 3 as indefinite under Section 112 (AX11 at 44-45),[5] ACS pointed to page 10, line 30 of the specification and told the Patent Examiner that this section "clearly explained the dimensions of the stent and the thickness of the various members making up the serpentine pattern 30 will dictate which of the U-shaped, W-shaped, and Y-shaped members that tip radially outwardly to form a projecting edge."[6] (*Id.* at 119). ACS told the Examiner that the shape of the cylindrical element of the Lau invention – *i.e.*, the "undulating pattern (*e.g.*, serpentine)" – consisted of a "plurality of U-shaped members 31, W-shaped members 32, and Y-shaped members 33." (*Id.* at 14).

In that same submission, ACS also argued that the amount of "projecting" required by claim 3 was not indefinite, but rather would be determined in part by the "thickness of the *various members* making up the serpentine pattern 30." (*Id.* at 119). By relying on the passage in the specification relating to U-shaped, W-shaped and Y-shaped members, ACS conceded that *all* embodiments covered by claim 3 would have some combination of these

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[5] Claim 3 is a dependent claim which adds the limitation of "outwardly projecting edges" to claim 1 of the '154 patent.

[6] The indicated portion reads: "Depending upon the dimensions of stent 10 and the thickness of the various members making up the serpentine pattern 30, any of the U-shaped members 31, W-shaped members 32, and Y-shaped members 33 can tip radially outwardly to form a projecting edge 34."

various members. ACS's argument to the Examiner again underscored that the "serpentine pattern 30" is necessarily part of the cylindrical element in claim 1. This explanation apparently satisfied the Examiner as to claim 3 because on June 19, 1995, claim 3 was allowed. (*Id.* at 127).

The Examiner also initially rejected claim 5 as indefinite. As filed, claim 5 required "some of said U-shaped, Y-shaped, and W-shaped members being interconnected." (*Id.* 21). In his objection, the Examiner said that he could not understand "what applicant considers the connecting elements if the cylindrical elements included such [U-, Y-, and W-] shaped members." (*Id.* at 44). Specifically, the Examiner stated, "it appears that the Y- and W-shaped members *are nothing more than part of the normal serpentine pattern* and further including the connecting elements attached thereto." (*Id.* at 44-45). In other words, the Examiner concluded that an undulating pattern made up of *only* U-shaped members cannot be an undulating pattern because there would be nothing connecting adjacent cylindrical elements. Instead, the Examiner observed, connecting elements must be attached at Y-shaped and W-shaped portions of the cylindrical element to connect adjacent cylindrical elements.

ACS did not suggest that the Examiner's understanding of the claim language was incorrect on this point. Instead, it amended claim 5 so that a portion of the Y-shaped members formed the connecting elements. Specifically, ACS amended claim 5 "to define the connecting elements as a portion of the Y-shaped members . . . As is clear, the tail portion of the Y-shaped members is the connecting element between the cylindrical elements." (*Id.* at 119). Again, ACS's statements to the Examiner specifically defined an undulating pattern in

terms of a combination of U-shaped members, W-shaped members and Y-shaped members.[7]

In view of ACS's added language and figures, and as a result of ACS's representations during prosecution, the Patent Office issued the four patents at issue. Each of these patents refers to "*closely spaced* cylindrical elements." (AX1 at 5:24-29; AX5 at 5:27-32; AX6 at 5:27-32; & AX7 at 5:30-35). And each includes the language added in the continuation-in-part application specifying that "[s]erpentine pattern 30 is made up of a plurality of U-shaped members 31, W-shaped members 32 and Y-shaped members 33." (AX1 at 6:12-14; AX5 at 6:15-17; AX6 at 6:15-17; & AX7 at 6:17-19). Each patent describes the stent of the invention as "a series of radially expandable cylindrical elements *which are spaced longitudinally close enough* [to support the vessel], *but not so close* as to compromise the longitudinal flexibilities of the stent." (AX1 at 2:1-6; AX5 at 2:7-12; AX6 at 2:6-11; & AX7 at 1:10-15).

C. By Urging The Court To Disregard The Specification And Prosecution History And Adopt A Claim Construction That Does Not Require A Combination Of U-, W- And Y-Shaped Members, ACS Invited Error

During *Markman* proceedings in this case, Medtronic urged the Court to incorporate the "spaced apart" aspect of ACS's invention into its claim constructions. Specifically, Medtronic proposed to construe "cylindrical element" (and related terms) to include "any combination of U-shaped, Y-shaped and W-shaped members." (D.I. 397 at 2 & 497).[8] It also

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[7] During trial, ACS argued that because some of the dependent claims mention U-, W- or Y-shaped members, they cannot be part of the definition of cylindrical element. ACS is wrong. The dependent claims address specific combinations of letter shaped members (in the case of claim 5—a plurality of U-shaped members, a plurality of Y-shaped members, and a plurality of W-shaped members (*i.e.*, all three letter shapes)) which are a subset of possible combinations that can form the serpentine pattern.

[8] During claim construction, the parties and the Court treated several sets of related terms as having the same meaning. Thus "cylindrical element," "cylindrically shaped element" and "cylindrical ring" were all given the same meaning.

(continued . . .)

proposed that claims reciting "connecting elements" *and* claims reciting "connections" be construed to require "[d]iscrete structural components of the stent that connect, extend between, and space apart adjacent cylindrical elements." (*Id.* at 2-3). Medtronic explained that, in view of the language of the specification and ACS's statements during prosecution, both the "connected" claims and "connecting elements" claims had to be construed to require spacing apart of cylindrical elements in accordance with the stent of the invention. (D.I. 420). Finally, Medtronic proposed that "weld" ("A weld connection that secures the end of a connecting element to the end of a cylindrical element") and "undulating pattern" ("A pattern that includes any combination of U-shaped, W-shaped and Y-shaped members") be construed to require spacing apart of cylindrical elements. (D.I. 397 at 3). In a later submission, Medtronic clarified that it intended this proposed construction to require a structure to have at least two of the three types of letter-shaped members to be a "cylindrical element." (D.I. 497).

In its January 5 claim construction, the Court construed "cylindrical element" to require "a circumferential undulating pattern." (D.I. 542 at 3-4). It construed the phrase "undulating pattern," in turn, to mean "a wavelike pattern that includes any combination of U-shaped, W-shaped or Y-shaped members," substantially as Medtronic had proposed. (*Id.*). The Court construed "connecting elements" to be "segments of a stent that extend between adjacent cylindrical elements, connecting them together" (that is, including "extend between" but not "spaced apart"). It construed "connected" as simply "connected." (*Id.*).

(. . . continued)

This was also true of "connecting elements," "connecting members," "interconnecting elements" and "struts for connecting," which were construed to have one meaning, and of "interconnected," "connected together," "connected," "attaching," "attaches" and "attached" which were construed to be synonymous. (D.I. 397 at 2-3).

On the same date, the Court granted summary judgment for ACS that Medtronic's S7 and Driver stents infringe claim 1 of the '133 patent on the grounds that "[p]ictures of the accused products reveal that the cylindrical elements are made up of a combination of U-shaped and *possibly* Y-shaped members." (D.I. 545 at 11).

Medtronic moved for reconsideration of the Court's grant of summary judgment, pointing out the fact dispute as to whether the S7 and Driver stents contained the required *combination* of "U-shaped, W-shaped or Y-shaped members." (D.I. 559). On February 2, 2005, the Court granted the motion, specifically noting that the "undulating pattern" limitation required at least two of the three letter-shaped elements. (D.I. 579).

The next day, without formally moving for reconsideration, ACS sent an e-mail to the Court questioning the Court's ruling. (*See* Exh. C (2/3/05 Cottrell e-mail to the Court)).[9] Medtronic responded the following morning, pointing out that ACS's belated attack was both improper and baseless. (*See* Exh. D (2/4/05 Louden e-mail to the Court)). On February 4 (two days after it granted Medtronic's motion for reconsideration and one court day before trial), the Court withdrew its construction of "cylindrical element" and directed the parties to present their claim construction arguments to the jury. (D.I. 587).

In its February 16, 2005 Order, issued just before the jury charge, the Court construed "undulating pattern" as "wavelike" rather than as requiring a combination of U-shaped, W-shaped and Y-shaped members. The Court indicated that it could not "reconcile the description of the inventions found in the specification with all of the claim limitations." (D.I.

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[9] ACS's e-mail raised arguments for the first time, including (a) that the Lau specification does not include the word "combination" and (b) the language the Court relied on to construe "cylindrical elements" as containing U's, Y's or W's was not included in the original Lau patent application (filed in 1991) but was added in prosecuting the '154 patent.

615 at 1). Noting that certain claims do not expressly require "connecting elements," the Court hesitated to require the presence of W- or Y-shaped members for such claims. (*Id.* at 2 & n.1). In effect, the Court sought to harmonize the language of the claims and de-emphasize the importance of statements in the prosecution history in coming to its claim construction. Medtronic respectfully submits that this approach is at odds with the line of recent cases from the Federal Circuit requiring the district courts to construe patent claims as one of ordinary skill in the art would do in view of not just the claims and the specification, but also the statements made to the Patent Office in order to get a patent issued. *See, e.g., C.R. Bard v. U.S. Surgical Corp.*, 388 F.3d 858 (Fed. Cir. 2004); *Astrazeneca AB v. Mutual Pharmaceutical Co.*, 384 F.3d 1333 (Fed. Cir. 2004); *Int'l Rectifier Corp. v. IXYS Corp.*, 383 F.3d 1312 (Fed. Cir., 2004). *See also Phillips v. AWH Corp.*, No. 03-1269, -1286 (Fed. Cir. July 21, 2004) (*en banc* Order) <http://www.law.upenn.edu/fac/pwagner/fedcir/claimconstruction/phillips_v_awh.en_banc_order.pdf>.

In fact, however, as explained in both the specification and file history, all claims do require such structure because, as discussed above, it is fundamental to the invention that the cylindrical elements *must be spaced apart*. Medtronic respectfully submits that if the Court were to construe "cylindrical elements" as wavelike, it was error not to construe other claim elements, such as "interconnected" and "connected," as including a requirement of spacing apart adjacent cylindrical elements. Only in this way can the claims, specification and prosecution history be reconciled. On the other hand, by reading out of the claims any requirement of spacing apart the cylindrical elements (except with respect to claims that also require a connecting member), the Court construed the claims inconsistent with the patent and prosecution history. Because the claims now have no requirement of spacing apart, they cannot be reconciled with the description of the invention. The jury verdict is thus based on

an improper construction and cannot stand.

D. Applying The Correct Construction, The Medtronic Stents Do Not Infringe Because They Do Not Have A Combination Of U-, W- And Y-Shaped Members

Medtronic's stents do not have W-shaped or Y-shaped members; they are made up exclusively of U-shaped members. ACS does not dispute this fact. [10] Dr. Jerome Segal, ACS's expert, testified that each unconnected ring of Medtronic's stents has only U-shaped members. (Trial Tr. at 566-567). Dr. Segal also agreed that there is no material added between the cylindrical rings of Medtronic's stents when they are joined by autogenous fusion welds. (*Id.* at 596). Finally, Dr. Segal admitted, after a series of questions on cross examination, that "if there's nothing extending between the two rings, you couldn't have a Y." (*Id*. at 623-627).

Without an "undulating pattern," Medtronic's stents do not have "cylindrical elements" and cannot infringe the Lau patents. As a matter of law, based on the proper claim construction and the uncontroverted testimony of ACS's own witnesses, Medtronic's stents do not meet the limitation of "cylindrical element" (or like terms) as required by each of the asserted claims of the Lau patents. Thus, as a matter of law, a judgment that Medtronic's stents do not infringe any of the asserted claims of the Lau patents is proper.

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[10] Indeed, ACS has acknowledged that the BeStent2 does not infringe under what Medtronic believes to be the proper construction of "undulating pattern." (*See* Exh. C. (2/3/05 F. Cottrell e-mail to the Court)).

II. MEDTRONIC'S STENTS DO NOT INFRINGE THE '154 PATENT BECAUSE THEY LACK THE NECESSARY "CONNECTING ELEMENTS"

Each of the asserted claims in the '154 patent requires "connecting elements." AX1, col. 8:43-46; 8:62-65; 9:28-34. The Court construed "connecting elements" (and synonymous terms) to mean "segments of a stent that extend between adjacent cylindrical elements, connecting them together." (D.I. 628 at 25). For the reasons pointed out above, given the language of the specification and statements ACS made to the Patent Office, it is also clear that any connector (or, for that matter, connection) must also space apart the cylindrical elements. Even under the Court's construction, however, ACS presented no competent evidence that any of the accused Medtronic stents have connecting elements that extend between (let alone space apart) cylindrical elements, and thus they do not infringe.[11]

A. Medtronic's Stents Do Not Have Connectors.

Unlike ACS's stents, Medtronic's stents do not have connectors. Rather, as Medtronic's Jeff Allen, Matt Birdsall and expert Dr. Ray Vito explained, Medtronic's stents are formed by welding the crowns of individual segments together at their tips with a laser. This process is known as "autogenous laser fusion" and does not add any new material (or "filler metal") to the device. *See* Trial Tr. at 788-791, 820-822, 829-831, 880-881, 904-905, 968, 970-975, 996-998, 1004-1008, 1098. For example, Mr. Allen testified: "There is no connector. There's a connection and that's that autogenous fusion weld that I've been talking about." *Id.* at 832. Similarly, Dr. Vito explained that "[t]here are no connectors between adjacent crowns." *Id.* at 971.

[11] Only literal infringement is at issue here as the Court granted Medtronic's motion for JMOL of no infringement by equivalents. (Docket Entry of 2/17/05 and Tr. at 1739:20-1740:1).

Mr. Allen a Medtronic engineer and stent designer since 1997, testified in great detail about the fundamental nature of Medtronic's rigid weld connections and the use of these weld connections to transfer bending loads. *Id.* at 818-19. Mr. Allen testified that Medtronic uses rigid welds to transfer the forces from one segment to the other and that the bending takes place within the segment itself. *Id.* at 797. He explained how the result of Medtronic's fusion welding is that "they [the crowns] push right into each other and actually occupy the same space, so that they are touching. They are beyond touching. They're actually occupying the same – the same space." *Id.* at 790, 792. If they did not occupy the same space, they would not be able to transfer the bending loads to the adjacent segments, which is fundamental to the design of Medtronic's stents. *Id.*

Mr. Allen's testimony about the nature of Medtronic's manufacturing process was also confirmed by Dr. Ray Vito, an expert in mechanical engineering with an emphasis on cardiovascular devices, and Mr. Birdsall, the man who originally conceived of the laser fusion welding used by Medtronic. Dr. Vito confirmed that "there's really no room between there for anything to come between the crowns other than the weld." *Id.* at 972. Both Mr. Allen and Dr. Vito testified that this process was illustrated by, among other things, a magnified photograph of the fusion weld (s*ee* DTX149A and 150A, Trial Tr. at 793-796, 975-979) which demonstrate that the weld connections do not occupy any space and do not extend between anything. Indeed, Dr. Vito testified at some length that the limitation of "extending between" was not met because Medtronic's products are:

> Put together so that there really isn't any space whatsoever between the adjacent elements or anything to extend between those elements. They're put together by a fusion weld process, which is specifically designed to keep the crowns in intimate contact and we show them pictures and we talked about pictures where it's exactly what is shown. *They are in intimate contact with absolutely no room for anything extending between*

adjacent cylindrical elements as asserted in this definition.

Id. at 1028-1029.

Despite this testimony, ACS argued at trial that the weld in the Medtronic stents (other than the BeStent2, which has no weld) is a "connecting element" as required by claims 1, 4, and 12 of the '154 patent. ACS based its argument almost entirely upon the testimony of Dr. Segal. But Dr. Segal is not an expert on welding. *Id.* at 565. He was neither familiar with certain types of welds nor able to identify different welds or their properties. *Id.* at 565-566. He admittedly had no expertise in what effect different types of welds would have on metallic structures, such as stents. *Id.*

Moreover, the sole basis for Dr. Segal's opinion that Medtronic's autogenous fusion welds are "connectors" was based on magnified photographs of Medtronic's stents from marketing material (versus scanning electron microscope magnifications). *Id.* at 429-432. On cross examination, however, Dr. Segal agreed that Medtronic's fusion welding process does not add any new material. *Id.* at 596. He also agreed that when you try to weld together and melt two things, you heat them up so that they fuse together. *Id.* at 597. Thus, Dr. Segal's testimony that Medtronic's stents have connectors flies in the face of his own admission that Medtronic's welding process does not add any new material.

Moreover, Dr. Segal never pointed to a weld that "*extended between* adjacent cylindrical elements." Instead, when asked to discuss his support for finding connecting elements in Medtronic stents, Dr. Segal merely stated that the welds were "between" the cylindrical elements. Like a magnetic attraction, however, autogenous welds can and do create a bond or connection "between" two objects without *extending* between them. Dr. Segal's testimony that the "extend between" limitation was met had no basis in the evidence, it was merely a conclusory opinion.

ACS also argued that the Medtronic products have measured dimensions in their specifications. The fact that the specifications set forth measurements, however, does not make the weld a discrete component and does not mean it extends between adjacent crowns. As Mr. Allen and Dr. Vito explained, Medtronic's specifications identify the "weld-affected area" of the crowns, not a discrete element inserted or created between them. Specifically, when asked about "Detail A," an illustration on a Medtronic design specification, Mr. Allen and Dr. Vito explained that the drawing that represented the weld was not a third part of the stent that was added to the two rings; it was not a connector but simply an illustration of the weld. *Id.* at 870; 980-987. Dr. Vito emphasized that "[t]here is no component connecting the two crowns." *Id.* at 987. Dr. Vito further explained that if there had been a component, the dimension of that component would have had to been spelled out in the specification. *Id.* There is no such description in the Medtronic specifications. Rather, it is a quality control specification of the weld to ensure that the operator welds in the correct place. *Id.* at 985-86. Again, this testimony was unrefutted.

Given the unrebutted testimony that there is no space between the segments of Medtronic's stents, no reasonable juror could conclude that Medtronic's weld connections either "extend between" or "space apart" the adjacent sinusoidal rings of Medtronic's stents.

III. MOST OF MEDTRONIC'S STENTS DO NOT INFRINGE BECAUSE THEY DO NOT MEET THE EXPANDABLE CYLINDRICAL ELEMENT WITH "LENGTH LESS THAN DIAMETER" LIMITATION

"To prove literal infringement, the patentee must show that the accused device contains every limitation in the asserted claims. . . If even one limitation is missing or not met as claimed, there is no literal infringement." *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998) (internal citations omitted). Each of the asserted claims of the

'154, '167 and '168 patents requires a "longitudinally flexible stent for implanting in a body lumen" made up of expandable cylindrical elements. The '133 patent recites a "longitudinally flexible stent" made up of cylindrical elements that have "a shape configured to enable the cylindrical element to expand."

According to the testimony of ACS's own expert, stents can generally be described in three states: crimped, expanded and "as manufactured" (also referred to as "neither crimped nor expanded"). *See, e.g.*, Trial Tr. 476:6-477:9. The evidence presented to the jury established that it is stents in their crimped state that are capable of "implanting" and able "to expand." Indeed, the only evidence that ACS presented at trial concerning the longitudinal flexibility and expandability of Medtronic's stents pertained to their crimped state.[12] For example, ACS's expert, Dr. Segal, was talking about crimped stents when he testified regarding infringement and longitudinal flexibility:

> Q. Let's look at the next slide. What do we see here?
>
> A. Photographs of all of these Medtronic stents we've been talking about and these were all still on the delivery system, so still on the balloon, basically, and they've been bent into kind of an S configuration to show they can approximate a curve very well. They're longitudinally flexible, inflexible [sic: flexible] along the length of the stent.

Trial Tr. at 466. As is clear from the testimony, the slide to which Dr. Segal referred showed Medtronic stents crimped on balloons. Moreover, Dr. Segal testified that the "length less than

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[12] There is no question that "longitudinally flexible" is a claim limitation. In its opening claim construction brief, ACS argued that the term "longitudinally flexible stent," although part of the preamble of the asserted claims, should be treated as a limitation. (D.I. 419 at 16-18). (ACS wanted it interpreted as a claim limitation to preserve its validity position regarding the Schatz '984 patent). ACS repeatedly pointed out that the patent requires a stent to be flexible because flexibility "facilitates delivery through tortuous body vessels." (*Id.*). The Court agreed with ACS and held that the term "longitudinally flexible" is a limitation.

diameter" limitation had to be satisfied by a cylindrical element that was also "expandable" (*Id.* at 443-444):

> Q. Why is it your belief that a cylindrical element needs to have a length less than its diameter?
>
> A. It's specific to the patents that they were all talking about. When they describe a cylindrical element, that's in the description of cylindrical element. I guess what we have here is an excerpt where it says that the *individually radially expandable cylindrical elements* of the stent are dimensioned so as to be longitudinally shorter than their own diameters.

The Court construed "longitudinally flexible stent" to mean "a stent that is flexible along its longitudinal axis (*i.e.* length) *to facilitate delivery* through tortuous body lumens." (D.I. 542 *Id.* at 2). Thus, the focus of Court's construction, too, is on deliverability. The Court also construed "cylindrical element" in pertinent part to mean "a *radially expandable* segment of a stent having a *longitudinal length less than its diameter* with a circumferential undulating pattern." (*Id.* at 2-3).

All of the asserted claims require *expandable* cylindrical elements. To show infringement, then, ACS had to establish that these crimped, flexible, expandable, deliverable stents, capable of being implanted, also had cylindrical elements. *This, ACS failed to do*. Because the length of Medtronic's stents (with the exception, according to Dr. Segal, of the Driver and MicroDriver) is not less than their diameter in the crimped, expandable state, they do not have expandable cylindrical elements.

Dr. Segal testified that he believed the Court's claim construction was silent as to *when* a stent had to meet the "length less than diameter" limitation. *Id.* at Trial Tr. 476:6-11. That is plainly incorrect. One skilled in the art would clearly understand that stents are only expandable and facilitate delivery through the body lumens in the crimped state. In other words, ACS had to show that the length of Medtronic's stents must be less than their diameter

in the crimped position, when the stent is capable of implantation and expandable, and when the "longitudinally flexible" limitation was shown to be met.

Dr. Segal admitted that *all* of Medtronic's stents, other than the Driver and MicroDriver, have longitudinal lengths *greater than* their diameters on the balloon in the crimped state (Tr. at 477):

> Q. Even crimped on the balloon, did some of the stents have length less than diameter?
>
> A. Some of them did. Some of them did not.
>
> Q. Some of them in the Driver did?
>
> A. Yes.
>
> Q. And MicroDriver?
>
> A. Yes, sir.

Rather than showing that Medtronic's crimped stents (*i.e.*, its flexible, expandable, deliverable stents) had cylindrical elements, ACS attempted to establish infringement by showing that Medtronic's stents had length less than diameter in other states. Neither Dr. Segal, nor anyone else, testified that the Medtronic stents were longitudinally flexible and expandable in any state other than the crimped state.

No reasonable juror, based on the record before the Court, could have concluded that the accused stents were both longitudinally flexible and radially expandable in anything but the crimped state. Yet there is no dispute that, with the exception of the Driver and MicroDriver, they do not have length less than diameter in these states. On this basis, the court should grant JMOL of non-infringement as to all products other than Driver and MicroDriver.

IV. THE COURT SHOULD ENTER JMOL OF NON-INFRINGEMENT BECAUSE ACS FAILED TO SHOW THAT MEDTRONIC MADE, USED, SOLD OR OFFERED FOR SALE ANY PRODUCTS DURING THE TERM OF THE PATENTS IN SUIT

A. ACS Had The Burden Of Showing That Medtronic Committed Infringing Activities During The Term Of The Asserted Patents As Part Of Its Prima Facie Case Of Invalidity

The movant is entitled to judgment as a matter of law "if the nonmoving party failed to make a showing on an essential element of his case with respect to which he had the burden of proof." *Singer v. Dungan*, 45 F.3d 823, 827 (4th Cir., 1995) (*quoting Bryan v. James E. Holmes Regional Medical Ctr.*, 33 F.3d 1318, 1333 (11th Cir. 1994)). At trial, even more so than in the context of a motion for summary judgment, a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, is subject to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

The patent law could not be clearer: "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention *during the term* of the patent therefore, infringes the patent." 35 U.S.C. § 271(a). Indeed, "[i]t is axiomatic that there can be no infringement of a patent prior to its issuance." *Cohen v. U.S.*, 203 Ct. Cl. 57, 59-60 (1973) (citations omitted); *see also Systematic Tool & Mach. Co. v. Walter Kidde & Co.*, 390 F. Supp. 178, 197-98 (E.D. Pa. 1975) ("Three separate elements must be established before there can be a finding of infringement: (1) the invention be made, used or sold (2) during the term of the patent (3) by one without authority to do so."), *rev'd on other grounds*, 555 F.2d 342 (3d Cir. 1977). ACS failed to prove every element of liability and, therefore, it is simply not entitled to proceed on

to damages.

Despite ACS's contention that it should be allowed to do so, and despite a diligent search for supporting authority, Medtronic has found no case in which a litigant was permitted to prove one of the elements of its infringement case as an "element of damages." While it is true that cases may be bifurcated and different issues may be tried to separate juries, infringement liability is a single, discrete issue and must be determined by a single jury. It would violate Medtronic's Seventh Amendment right to jury trial to divide the issue of infringement between separate trials in such a way that the same issue is reexamined by different juries. *See Brown v. SEPTA (In re Paoli R.R. Yard PCB Litig.)*, 113 F.3d 444, 453 (3d Cir. 1996) (quoting *In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1303 (7th Cir. 1995)). *See also Smith v. Alyeska Pipeline Service Co.*, 538 F. Supp. 977, 986 (D. Del. 1982) (stating that it would violate a party's Seventh Amendment right for a first jury to determine whether defendants infringed the patent and a second to determine the state of mind of defendants when they infringed the patent since the damage jury would have to pass over many of the same issues that were presented to the liability jury to determine the defendants' state of mind).

If the Court were to proceed as ACS now proposes, and allow a second jury to find an essential element of infringement, two separate juries will have to decide portions of this issue. This would not only violate the order of proof set by the Court in bifurcating this case into liability on the one hand and damages and willfulness on the other, it would also violate Medtronic's Seventh Amendment right to a jury trial.

B. ACS Invited JMOL When It Refused Its Opportunity To Remedy This Gap In Its Evidence

On February 9, Medtronic moved for JMOL after ACS rested its case in chief on

infringement, pointing out (among other things) that ACS had failed to demonstrate that Medtronic had made, used or sold its products during the term of the patents, as required by Section 271. ACS declined to ask to reopen evidence so it could submit proof on this issue.

ACS presented its rebuttal case on February 15, but again failed to put on any evidence on this issue. On February 16, ACS rested and Medtronic again moved for JMOL on this (as well as other) grounds. Again, ACS failed to seek leave to offer evidence on the "timing" of Medtronic's sales relative to the term of the asserted patents.

ACS was well on notice that it would have to prove this element of its claims. Although the Pre-Trial Order had contained the admitted fact of manufacture and sales in general, the question of *when* those sales had taken place was not admitted.[13] ACS nonetheless argued that the "timing issue" was a damages issue and should be addressed only if there were a finding of infringement. (Trial Tr. at 1698). In response, the Court said:

> THE COURT: Already. So are you honestly suggesting that after these companies paid this million – this many hundreds of thousands of dollars on this trial, that you are suggesting there's a complete lack of evidence on timing and, therefore, it does not go to the jury at all because ACS has not demonstrated when each of these products were on the market?
>
> MR. RIZZO: Yes, your Honor. Quite simply, yes. That's their burden. They have to demonstrate when these products were made, used or sold. It's in 271.

(*Id.* at 1700).

> THE COURT: Well, if they didn't – I guess I want you to address the issue. Even if they said for purposes of damages, X product does not infringe one patent, wouldn't they still need to prove whether or not – I don't know, the noninfringing

[13] Indeed, the question had become much more sharply focused only *after* submission of the Pre-Trial Order, when ACS at last shared the list of asserted claims it actually intended to pursue at trial, and it had dropped three of its earlier patents from the list altogether.

> alternative – I don't know. Wouldn't there still be some use for knowing whether these products infringe these patents or not? In other words, we're not going to go through another infringement case in the –
>
> MR. RIZZO: I understand that, but they are not infringing if the patent hasn't issued. The products can't be infringing if the patent hasn't issued.

(*Id.* at 1702).

The next day, the Court concluded that "[w]ith respect to timing, I have determined that's really a damages issue. There's no evidence in the record. The jury would not even know what to do with that issue. And because it is really a damages issue, that is not going to the jury." (*Id.* at 1740). The fact that there was no evidence in the record, however, was based on a failure of proof of ACS. JMOL should have been entered for Medtronic because there was no evidence before the jury, but the Court in effect granted JMOL to ACS instead.

ACS's failure of proof was highlighted during the jury deliberation. The jury asked the Court and counsel to answer the following question: "To determine infringement, do you use the date the patent was issued, *i.e.*, date of patent?" (*Id.* at 1899). Initially, the Court, ACS and Medtronic agreed that the correct response was "yes." (*Id.* at 1900). Several minutes later, however, in the context of another question posed by the jury, ACS raised the earlier question and answer with the Court, and asserted that the jury may have been confused by a statement in Medtronic's closing that pointed out that certain ACS patents were issued after Medtronic started selling its products. ACS argued: "[f]or the infringement analysis, it is really irrelevant because they're entitled to the filing date of 1991. But [ACS] is concerned after thinking about it that they are asking about the date of the patent, they may think it's somehow relevant that Medtronic started selling its product with welds before we had an issued patent that claimed a stent that covered welds." (*Id.* at 1912). However, whether

Medtronic sold its products before or after the patents issued, was indeed, a relevant inquiry under the patent law. A product cannot infringe a patent before it is issued and a discontinued product cannot infringe a later-issued patent.

The Court ruled that it was improper for the jury to base infringement decision on the date of the patent. (*Id*. at 1913-1914). The Court then proposed the following instruction: "It is improper for you to base any decision as to infringement on the dates the patent issued." (*Id.*). Medtronic noted that 35 U.S.C. § 271(a) requires one to make, use, offer to sell or sell a product *during the term of the patent* to be liable for infringement. (*Id*. at 1914). Despite Medtronic's argument and the requirement set forth in 35 U.S.C. §271(a), the Court insisted that the "concern will be addressed in the damages case. Right now, I'm just having the jury determine whether the stents meet the limitation of the claims." (*Id.* at 1915).

C. Because ACS Had To Prove That Medtronic Made, Used, Sold, Or Offered For Sale, The Accused Products During The Term Of The Patents, The Jury's Infringement Finding Has No Basis In The Record

ACS's failure to establish that the accused products were made, used, sold or offered for sale after issuance of the patents was not harmless. While it was not Medtronic's burden to do so, Medtronic provided a proffer which conclusively demonstrated that ACS *could not prove that* (1) the MicroStent II infringes the '167, '168, or '133 patents; (2) the GFX infringes the '167, '168, or '133 patents; (3) the GFX2 infringes the '167, '168, or '133 patents; (4) the GFX 2.5 infringes the '133 patent or (5) the S540 infringes the '133 patent. (D.I. 626). Medtronic's unrefuted proffer establishes that jury found infringement of products that *cannot* infringe as a matter of law because they were sold only *before* at least some of the asserted patents issued. (Trial Tr. at 1697-1700). Because the Court instructed the jury that it could not consider dates, however, the Court's ruling virtually assured a verdict for ACS,

rather than Medtronic.

Because no reasonable juror could have found infringement of the Lau patents by Medtronic's stents based on the evidence presented at trial, the Court should grant JMOL of non-infringement.

V. ACS FAILED TO SHOW THAT IT OWNS THE LAU PATENTS

A. Though ACS Offered An Assignment Into Evidence It Did Not Constitute Evidence Of Ownership Of The Patents In Suit

Showing ownership of an asserted patent is the fundamental requirement to satisfy the Constitutional requirement of standing. *Pandrol USA, LP v. Airboss Ry. Prods.*, 320 F.3d 1354, 1367 (Fed. Cir. 2003). Moreover, under Article III, "standing . . . is jurisdictional and not subject to waiver." *Id.*, (quoting *Lewis v. Casey*, 518 U.S. 343, 349 n.1, 135 L. Ed. 2d 606, 116 S. Ct. 2174 (1996)). It is thus a basic principle of patent law that a party who lacks legal ownership of a patent is without standing to sue for infringement of that patent. *FilmTec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572 (Fed. Cir. 1991) (a party who lacked patent title would be without "standing to bring the present action"); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991) (a party who assigned all of its ownership in a patent has no "right to sue for infringement"). Furthermore, the party invoking federal jurisdiction bears the burden of establishing the elements of standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Thus, to maintain this suit for patent infringement, ACS was required to forth facts sufficient to establish its ownership of the patents at issue.

ACS accused various Medtronic stents of infringing four patents. Of these, the '154 patent issued the earliest, from the continuation-in part ("CIP") '790 application. Each of the

remaining patents (the ’167, the ’168, and the ’133 patents) all issued from continuations relating back to the same ’790 application that resulted in the issuance of the ’154 patent. The ’154 patent application was a division of U.S. Ser. No. 08/164,986, abandoned. This abandoned application was itself a continuation of the ’558 application, also abandoned. This “original application” was the grandparent of the ’154 patent.

ACS obviously recognized that it needed to prove ownership, because it offered a patent assignment into evidence.[14] The assignment ACS offered, Exhibit AX-912, however, was the assignment of the *original abandoned application* (the ‘558 application) and not the ’790 application that led to the ’154 patent. By definition, the later ’790 application, being a continuation-in-part of the earlier application, necessarily contained *additional* subject matter not a part of the grandparent application. Simple logic dictates that the assignment of an earlier set of ideas cannot, alone, effectively transfer rights in ideas only later incorporated into a new application, no matter how many of the older ideas are carried forward. Thus, Exhibit AX-912 did not assign ’154 patent (or later patents) to ACS. With respect to the key application (the ’790 application), ACS simply failed to show ownership of the patent application that matured into the ‘154 patent.

The principles governing patent ownership laid out in the Manual Of Patent Examining Procedure (M.P.E.P.) confirm this fact. The M.P.E.P. explains the process for granting and obtaining assignments to patents as follows:

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[14] Indeed, ACS was well on notice that it needed to prove ownership, as Medtronic listed as an issue that remains to be litigated in the Pretrial Order “the assignment of the Lau patents-in-suit to ACS.” (D.I. 538, Exh. 2 at 4). When the other defendants in the Boneau cases Medtronic on notice that it would have to prove ownership of its patents, Medtronic put ACS on notice that it would have to prove ownership of the Lau patents as well.

> In the case of a substitute or continuation-in-part application, *a prior assignment of the original application is not applied to the substitute or continuation-in-part application* because the assignment recorded against the original application gives the assignee rights to only the subject matter common to both applications. *Substitute or continuation-in-part applications require a new assignment if they are to be issued to an assignee.*

M.P.E.P. §306.

While the M.P.E.P. is not judicially controlling law, this passage demonstrates that the Patent Office would not recognize any assignment in a parent application to continue into a CIP application. This is plain common sense. Because the continuation-in-part application contains new elements – elements not originally claimed in its parent – an inventor cannot possibly be deemed to have already assigned inventions not yet invented based on a prior assignment of the parent application. Any other rule would deprive the inventor of any right to freely assign new inventions.

Notwithstanding that Medtronic raised this issue in its JMOL at the close of ACS's case in chief on infringement, ACS did nothing to supplement the record before the case went to the jury. (D.I. 598). ACS did belatedly seek judicial notice of another assignment, purporting to assign an interest in the '790 application. (D.I. 623) That request, however, was too little and too late. The purported "evidence" was never presented to the jury and, so, could not possibly have formed a basis for a reasonable juror to conclude that ACS owns the patents in suit. And in any event, the record of the trial and the Court's docket reflect that the Court never granted ACS's request.

Without proof of ownership, ACS has failed to establish its standing to maintain this action. For this reason, Medtronic requests that the Court enter judgment as a matter of law.

VI. ACS PRESENTED INSUFFICIENT EVIDENCE TO REBUT MEDTRONIC'S CLEAR AND CONVINCING SHOWING THAT THE INVENTIONS CLAIMED IN THE LAU PATENTS WERE OBVIOUS

A. The Appropriate Legal Standard

1. Judgment As A Matter Of Law

No reasonable jury could have failed to find, based on the evidence presented, that the Lau Patents are invalid due to obviousness because ACS presented no competent evidence to rebut Medtronic's clear and convincing showing.

The question is not whether there is "literally no evidence" supporting the non-moving party, *Lifescan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 345, 350-51 (D. Del. 2000), but whether the evidence *reasonably* supports the jury's verdict. *Gomez v. Allegheny Health Servs., Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995). To overcome a motion for judgment as a matter of law, the non-moving party must point to "substantial evidence" to support a finding in its favor. *See Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1329 (Fed. Cir. 1991). Substantial evidence is the quantum evidence that reasonable jurors would accept as adequate to support the finding under review. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984). Merely "offhand and conclusory statements" are not sufficient to overcome the motion. 952 F.2d at 1327. Because ACS presented no rebuttal evidence to counter Medtronic's clear showing, JMOL is appropriate.

2. Legal Standard For Invalidity Based On Obviousness

The party asserting invalidity must prove that a patent is invalid by clear and convincing evidence. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291-292 (Fed. Cir. 1985). If the alleged infringer presents a *prima facie* case of

obviousness, the patentee must then rebut that evidence with its own evidence of nonobviousness. *Id.* at 291-92.

One way to invalidate a patent is to prove that the claimed invention was obvious under Section 103, which states:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a).

While the ultimate conclusion as to whether a patent is obvious under 35 U.S.C. § 103 is a question of law, the resolution of this question involves an analysis of underlying factual issues. Facts relevant to an obviousness analysis include: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) where relevant, objective evidence of nonobviousness such as long-felt need, commercial success, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966) ("the Graham factors"). *See also* Trial Tr. 1891-92 (Court's instructions to the jury).

B. Medtronic Offered Clear And Convincing Evidence Of Invalidity

This case presented an unusual circumstance in that much of Medtronic's invalidity case was essentially undisputed. It was agreed by both parties that those skilled in the art were seeking to design strong, yet flexible stents. It was also agreed that to achieve these objectives, the art had been moving in the direction of shorter elements, and that those in the art understood that short elements could be connected together to avoid migration problems.

There also was no dispute concerning the level of ordinary skill in the art, which both Drs. Saigal and Segal applied. Medtronic's expert, Dr. Saigal, provided testimony establishing where each and every element of the asserted claims were found in the prior art. Having established these facts, the burden shifted to ACS to rebut this evidence. However, ACS's expert, Dr. Segal, provided no such rebuttal. To the contrary, it was clear that the art had been moving in the direction of ever shorter elements and also in the direction of connecting elements. The central dispute was over whether one skilled in the art would have used connectors to combine the short Boneau elements described in the Boneau '331 patent.

As noted above, for each of the Lau patents, Dr. Saigal showed that the prior art patents contained certain elements, that when combined, would make the Lau patent obvious. His testimony related to the elements of the claims are found in the trial transcript from pages 1253-1378. For the '154 patent, Dr. Saigal testified that claim 1, claim 4, and claim 12 were obvious over the prior art of Boneau, Schatz and the Spiral Palmaz. (Trial Tr. 1353-1354; 1354-1355; & 1355). Dr. Saigal demonstrated how the Boneau and Spiral Palmaz patents disclose each and every claim limitation of claims 1, 4, and 12. Dr. Saigal also showed that the Boneau and Schatz '984 patents disclose each and every claim limitation of claims 1, 4, and 12. It would have been obvious to combine these patents, as they were both drawn to similar subject matter.

For the '167 patent, Dr. Saigal testified that claim 5 (*id*. at 1357-1358) and claim 8 (*id*. at 1358-1359) were obvious over the prior art of Boneau, Schatz, Wolff and the Spiral Palmaz. Dr. Saigal demonstrated that the Boneau and Spiral Palmaz patents disclose each and every claim limitation of claims 5 and 8. He also demonstrated that the Boneau and Schatz '984 patents disclose each and every claim limitation of claims 5 and 8. In addition,

Dr. Saigal also showed that the Boneau and Wolff '404 patents disclose each and every claim limitation of claim 5.

For the '168 patent, Dr. Saigal testified that claim 1 (*id.* at 1359-1360), claim 3 (*id.* at 1360-1361), and claim 11 (*id.* at 1361) were obvious over the prior art of Boneau, Schatz, Wolff, the Palmaz '665 patent, and the Spiral Palmaz. Dr. Saigal testified that the Boneau, Spiral Palmaz, and Wolff patents together disclose each and every claim limitation of claims 1, 3, and 11. Dr. Saigal also showed that the Boneau, Schatz, and Wolff patents together disclose each and every claim limitation of claims 5 and 8. In addition, Dr. Saigal showed that the Palmaz '665 patent, which was incorporated by reference into the Lau patents, could be substituted for the Wolff patent under the same combinations as above.

Finally, in the '133 patent, Dr. Saigal testified that claim 1 (*id.* at 1362), claim 2 (*id.* at 1362-1363), claim 3 (*id.* at 1363-1364), and claim 11 (*id.* at 1364) were obvious over the prior art of Boneau, Schatz, Wolff, the Palmaz '665 patent, and the Spiral Palmaz. Dr. Saigal showed that the Boneau and Spiral Palmaz patents together disclose each and every claim limitation of claims 1, 2, and 3. Dr. Saigal also showed that the Boneau and Schatz '984 patents combined to show each and every claim limitation of claims 1, 2, and 3. For claim 11, Dr. Saigal showed that Boneau and Schatz or Boneau and Spiral Palmaz, combined with either the Wolff or Palmaz '665 patent, contained each and every limitation. Thus, each of the claims asserted has been shown to be obvious over a combination of prior art references.

Dr. Segal, ACS's expert, essentially agreed with Dr. Saigal. In his redirect examination, Dr. Segal testified to the difference between the prior art and Lau's design:

> Q. Hi. We just heard a lot of cross-examination and a lot of it had to do with the fact that in the prior art, the assertion that in the prior art, it was known sometimes, instead of having one long stent, to use two shorter stents. Was that, indeed, done?

A. Yes, sir.

Q. And the example we kept seeing again and again was multiple Palmaz stents, and we started out, is that right, with the 15-millimeter Palmaz stent?

A. That would not [*sic*] correct, yes.

Q. And then it was known that you could use two 7- millimeter Palmaz stents?

A. That's correct.

Q. Do you dispute that that was known?

A. No, sir.

Q. *What is the difference between doing this and doing what ACS taught?*

A. That was completely different. That – that represents taking individual stents that function as stents, hooking them together, leaving them separate. *The ACS teaching is to use the cylindrical elements that are not in and of themselves stents and to use those to form a longitudinally flexible stent.*

Q. And why does that matter?

A. It matters because the properties of getting a longitudinally flexible stent that you can flex along its length and you can deliver to tortuous vessels, it's the – the construction of it is critical in those short cylindrical elements in those connectors.

Trial Tr. at 1673-1674.

In other words, the basis on which Dr. Segal distinguished the prior art of Palmaz from the Lau design was that the Palmaz elements were not in and of themselves stents. At the same time, however, Dr. Segal acknowledged that Dr. Palmaz himself developed shorter and shorter "elements" and also added connectors:

Q. If we could go back to the last slide that we saw during your direct testimony, sir, we see the Palmaz '417 on the left, the Schatz '984, the Wolff '404, Furui and Boneau. Do any of those in your opinion render invalid any of the claims of the ACS patents?

> A. Absolutely not.
>
> Q. What is fundamentally different about each and every one of those on the left than what ACS claimed in its patents?
>
> A. Everything on the left which was present in the prior art represents stents. They're either connected or they're unconnected, but they are each individual units. Each function as a stent and none of them are longitudinally flexible. What you see on the right is the ACS stent based on the teachings of the patent and that has shorted [sic] cylindrical – longitudinally flexible.

Trial Tr. at 1675.

Dr. Segal, therefore, agreed again that not only Palmaz, but other stents such as Wolff and Furui showed connectors. Again, Dr. Segal argued that the prior art stents were stents in and of themselves to distinguish them from the Lau design.

Whether the prior art stents were or were not "in and of themselves stents" was all a red herring, however. As noted, it was undisputed that it was well understood in the art that using shorter elements would improve flexibility. As Dr. Segal acknowledged the fact that Palmaz wasn't shortened further was not due to Dr. Schatz's lack of desire to do so or based on any reluctance to subdivide the stent. Rather, as Dr. Segal admitted, it was based on the Palmaz geometry, which did not permit it to be shortened further. Particularly, Dr. Segal testified:

> Q. So what the engineers were telling Dr. Schatz is, look, if we go shorter, it's not going to be wide enough, it's not going to have the diameter to match the vessels we're trying to treat?
>
> A. I think what they are telling him is that, based on the design of the Palmaz/Schatz, you've got to have that diamond configuration to get the support of a stent, *and that the shortest they could build with that configuration was 7 millimeters.*
>
> Q. Right. But the reason they could not go, the reason they said is because to get the diameter we wanted, the words they used, they couldn't do it?

> A. That's what they state. That's correct.
>
> Q. So the problem was if you go shorter, you wouldn't be able to get the diameter to work with the blood vessel?
>
> A. *I think what they are stating is that they couldn't build a stent that was shorter than 7 millimeters, the vessel range that they were talking about.*

Trial Tr. at 1640.

The Palmaz design, then, had reached its minimum length, as Dr. Segal testified. Thus, while it was understood that it was advantageous to create smaller cylindrical elements, the Palmaz design could not be made shorter and still work. Nonetheless, Dr. Segal agreed that Dr. Schatz understood at the time Lau was filed that shorter and connected stents were desirable:

> Q. Thank you. Would you agree with me, sir, that by requesting shorter stents, as short as possible, Dr. Schatz showed that he grasped the concept that it would be a good idea to use short connected stents?
>
> A. Yes, sir.

(Trial Tr. at 1658-59).

Dr. Segal also acknowledged that it was understood at the time connectors helped to keep a stent from migrating.

> Q. If you have two unstable structures, problems with them moving around, if you connect them, that cures the instability. Dr. Schatz understood that, didn't he?
>
> A. Dr. Schatz was talking about two stents not migrating in relationship to each other, moving.

(*Id.* at 1659-60).

Before Mr. Lau filed for his patent, however, Mr. Boneau had already invented a different design that could be made shorter and did not have the limitations of the Palmaz

geometry. Dr. Segal admitted that the Boneau 1 millimeter ring could be expanded to the proper vessel diameter (Trial Tr. at 1643):

> Q. All right. So let's talk about this 1-millimeter thing, this balloon expandable and it has a sinusoidal shape.
>
> Now, that thing can be opened up to the necessary diameters that you need to fit inside blood vessels?
>
> A. I'm just thinking about this for a second. If you are talking about a 1-millimeter thing, you could probably blow it up to be a solid ring, if you wanted to also. So you could probably make it pretty big. That's correct.

In sum, Dr. Segal's testimony, which was entirely consistent with Dr. Saigal's testimony, confirmed that it was known that shorter elements improve flexibility and that connectors help with stability. Dr. Segal also testified that connectors were known, and Mr. Boneau disclosed a structure (a "thing") that could be made 1mm in length and could expand to diameters effective for the vessels stents normally treat. Whether the Boneau 1 mm ring would, in and of itself, be considered a stent was irrelevant to the obviousness analysis. That is because the combination of a short Boneau element with any of the prior art that disclosed connecting stents renders the Lau design obvious to one of ordinary skill in the art, particularly in light of the uncontested motivation in the art to shorten stents to improve flexibility. The unrefuted evidence was that the Boneau stents disclosed in the '331 patent did not have the inherent design limitation of Palmaz which made smaller elements infeasible.

In addressing the motivation to combine, Dr. Segal's testimony shows that any person of ordinary skill in the art with the prior art in front of him or her would know that shorter lengths increase flexibility and connectors increase stability (or, decrease migration). This is entirely consistent with the testimony of Dr. Kahn, ACS's medical expert, that "shorter and connected" was desirable in the early 1990s.

> Q. So did interventional cardiologists understand in the early 1990's that one way to achieve better flexibility was to use shorter units?
>
> A. There were other ways, but that was certainly understood, I think, by anyone working in this field, that if you wanted to make the stent flexible, which it had to be for us to use in practical terms, you could make the sub-units shorter.
>
> Q. And did interventional cardiologists also understand that one way to, when you talk about not pulling the stents apart or destabilize the stents, that one way to do that was with connecting the stents together?
>
> A. Yes. I think we recognize the problem of independent units and connecting them was a way to solve a whole other set of problems.

Tr. at 718-19. Thus, there is no dispute – both Medtronic's and ACS's experts agreed.

Because ACS did not rebut Medtronic's clear and convincing showing of obviousness, Medtronic should be granted JMOL that the claims of the Lau patents are invalid.

CONCLUSION

For the foregoing reasons, Medtronic respectfully requests that its motion for judgment as a matter of law be granted.

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CERTIFICATE OF SERVICE

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